FDA Webinar: FDA Innovation Challenge:
Devices to Prevent and Treat Opioid Use Disorder
Moderator: Irene Aihie
July 25, 2018
1:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer of the call. To ask a question during that time, please press star followed by number one.

Today's conference is being recorded. Any objections, you may disconnect at this time. Now I'd like to turn over the meeting to (Irene Aihie). You may begin.

(Irene Aihie): Hello and welcome to today's FDA webinar. I am (Irene Aihie), of CDRH's Office of Communications and Education. Today we will focus on the FDA's Innovation Challenge for Devices to Prevent and Treat opioid use disorder, which was announced on May 30.

The goal of the challenge is to spur the development of medical devices -- including digital health and diagnostic devices -- to help combat the opioid crisis. And to help prevent and treat opioid use disorder, a serious health condition which can be a devastating outcome of opioid drug use.

The FDA's Center for Devices and Radiological Health will assess applications for this challenge through September 30, 2018. Doctors (Michelle Tarver) and (Johnathan Jarow) from CDRH will discuss and answer questions about the Innovation Challenge.

Following the presentation, we will open the line for your questions related to information provided during the presentation. Now I give you (Michelle).

Dr. (Michelle Tarver):Good afternoon. During the webinar today we will briefly cover the opioid epidemic, and we will give an overview of the FDA's efforts to combat the crisis. We will provide information about the Innovation Challenge and tips for potential applicants. We will leave time at the end of the presentation to answer any questions that you may have.

As you may be aware, the opioid epidemic affects 11.5 million people in the United States, with 11.5 of them misusing opioids and 2.1 million suffering with opioid use disorder. This condition impacts not only the individual with opioid use disorder but also their families and their friends. Unfortunately, opioid use disorder also leads to deaths from overdoses.

One factor associated with this epidemic is the increased availability of opioid medications over the past few decades. This practice of increasing prescribing has contributed to widespread misuse of both prescription and non-prescription opioids before it became clear that these medications could indeed be highly addictive. In 2017 the Department of Health and Human Services declared the opioid epidemic a public health emergency and announced a five-point strategy to combat the opioid crisis.

The five prongs of this strategy include improving access to treatment and recovery services. Strengthening public health surveillance. Advancing the

practice of pain management. Better targeting the availability and distribution of overdose reduce - reversing drugs. And supporting cutting-edge research. As part of the Department of Health and Human Services, the Food and Drug Administration remains committed to addressing the national crisis of opioid addiction on all fronts.

FDA has focused on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies and developing opioids that are more resistant to abuse and misuse; as well as taking action against those who contribute to the illegal importation and sale of opioid products.

The FDA will also continue to evaluate how drugs currently on the market are used -- in both medical and illicit settings -- and take action where needed. This Innovation Challenge is part of the FDA's ongoing work to reduce the scope of the opioid crisis and supports several of the overarching goals of the US Department of Health and Human Services five-point strategy.

In the past few years, the FDA has cleared, granted, or approved more than 200 devices related to the treatment or management of pain. This includes ten with new or novel technologies, such as brain and spinal cord stimulators that can relieve pain and reduce the need to administer opioid drugs to patients suffering from either acute or chronic pain.

The FDA also recently granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal. With these many existing devices, the FDA remains committed to encouraging innovation both in the diagnosis and treatment of chronic pain as well as opioid use disorder. That brings us to the CDRH Innovation Challenge.

Dr. (Jonathan Jarow): Thank you (Michelle). And good afternoon to everyone. The goal of the Innovation Challenge is to foster innovative and creative approaches for the use of medical devices in combatting this US opioid crisis.

We want to encourage development of non-opioid treatments for both acute and chronic pain. And we want to expedite both the development and review of innovative, safe, and effective medical devices that either help prevent or treat opioid use disorder.

Eligibility for this challenge includes any medical device that prevents or treats opioid use disorder. And this would include diagnostic devices, therapeutic devices, digital health technology -- such as mobile medical apps -- and combination products as long as the primary mode of action is by the device. Medical devices at any stage of development are eligible. Applicants can be either US-based or foreign, but when a foreign applicant applies they have to recognize that -- per our laws -- foreign firms will need a US representative to market a medical device in the United States.

The submission application should describe the intended use of the device. How the device technology is novel, in both design and concept. Should share with us the development plan for the medical device as well as the development information that's been gathered to date.

Describe the development team. Describe the anticipated benefit of the device and its impact on public health as compared to other alternative therapies. Other factors that will be taken into consideration in the review by FDA of these applications include feasibility of the device or concept. And the potential impact of participation within this program and receiving increased interactions with the FDA.

In terms of the timeline -- as you've heard earlier -- applications must be submitted electronically to the Food and Drug Administration by September 30, 2018. And these should be submitted via the mailbox shown on this slide. We intend to announce the applications selected for the challenge in November of 2018.

What should you expect if your application is selected for the Innovation Challenge? There will be an initial development phase -- where there'll be a lot of interactions between the review staff of CDRH and the device developer -- which will culminate -- hopefully -- in a pre-market application. And you will receive expedited review of that pre-market application.

Tips for potential applicants include you may submit multiple applications if you have more than one eligible device. FDA will not review device applications during the application time period or prior to the submission deadline of September 30, 2018.

We will not provide specific advice to Challenge applicants, but if your device concept meets the Challenge criteria, please submit an application. To remind you there is no official application form to fill out online. The format of the application is described on the Challenge website, and gives information as to the content as well as the format of these applications that should be submitted via the email box.

So, these are some resources that you could go to. We have the website address for the Challenge. We have a website that gives device advice on regulatory issues. As well as for mobile medical applications. And then, as well, a page on the website that discusses breakthrough devices.

(Irene Aihie): And we'll now open the line for questions.

((Crosstalk))

Coordinator: Thank you...

Dr. (Jonathan Jarow): Well as we're opening the line for questions, I wanted to go over some of the most frequently asked questions that we've received to date. One is whether or not there is cash prize as part of this FDA Challenge. There is not any cash associated with being accepted into the Challenge.

Another issue that's come up and has been addressed in this presentation is whether you have to be US-based company. And the answer to that is no. To apply for the Challenge, you do not have to be US-based. Combination products are eligible, it's just critical that we regulate it as a device so that the combination product has the primary mode of action through the device component.

And then the other key question is how to apply? The application is to be sent to FDA via email. Hopefully we now have the lines open so we can receive your questions.

Coordinator: Thank you. We will now begin the question and answer session. If you'd like to ask a question, please press star one and record your name clearly. One moment please while we wait for the first question. (First) question comes from (Eric Fannon). Your line is open.

(Eric Fannon): Yes, hello. My question is about what branch or division will take the lead of these applications as they're sent in. Is there a panel that's been put together? Or, you know, be interested to hear your comments on who's actually making the decision on whether you're accepted into the program or not.

Dr. (Jonathan Jarow): Yes, the review of the applications will be done by an internal panel. And then if an application's accepted it will go to the review division that that device is regulated by. So - but the panel will be composed of members from a variety of divisions within the agency, both in CDRH and CDER.

(Irene Aihie): We'll take our next question.

Coordinator: Question comes from (Dmitri). Your line is open. Please check your mute button, your line is open.

(Dmitri): Hello. Yes, can you hear me? I wanted to ask a question about one of the points of the application form, which talks about the impact on the public health. I would assume that quite often would be very hard to quantify appropriately. What is the expectation of the agency on that section of the application?

Dr. (Jonathan Jarow): We would hope that you would make your best effort to put your best foot forward in describing what aspect of opioid use disorder that this device would address. The potential population that would benefit. The -- based on either a concept or on actual clinical evidence -- what the impact would be on this device on that aspect of opioid use disorder.

And particularly if it involves any specific populations, vulnerable populations et cetera that may benefit from it. This is your opportunity to describe the device and what you perceive is the potential impact on this public health problem.

((Crosstalk))

Coordinator: Our next question comes from...

(Irene Aihie): We'll take the next...

Coordinator: ...(Atika). Your line is open.

(Atika Permasherin): Hi. I'm (Atika Permasherin). And I'm working on a startup called (unintelligible) Start, where we are building a therapeutic device for mothers suffering from opioid addiction and to help them not give in to relapse.

My question is, I did see that the device could be at any stage for you to apply. Now we are in a really early stage, and we are actually working at ground funding and other opportunities. And this is really intriguing and we would like to apply. Do you think, you know, we would fit this? Or we need to wait until we have sort of a prototype in place?

Dr. (Jonathan Jarow): Yes, as I stated in the presentation any stage of development is acceptable for this Challenge. So, it could be anything from a concept to an already-marketed device might be eligible for this Challenge.

So yes, a concept or early stage development device would certainly be eligible. And that would, you know, certainly have a greater impact about FDA involvement in the development process. The longest part of a device development -- from you know, concept to getting to market -- is actually in the development phase. Not the review phase of the eventual market application. And so, we could have a greater impact.

On the other hand -- in terms of evaluating feasibility -- the further on in development the device is the more feasible it may possibly be. So those would be the factors. But your project would certainly be eligible.

(Atika Permasherin): Okay, great. Thank you so much. And I just have a follow-on question, is it okay to ask that?

Dr. (Jonathan Jarow): Yes.

(Atika Permasherin): All right. So, the other question I had is, there's a bit of an ambiguity -- at least for me -- as I read through the website and so on of devices that are more digital or technology-focused.

Like if you're having a delivery platform for some kind of a therapy but you're providing some augmented tools and use for this particular segment. Is that considered as something the FDA's, you know, going to be more interested in being involved? Because I have seen other companies -- like Bayer Therapeutics and others -- you know, working on digital therapeutics.

So, we are trying to figure out if that is the path for us. And we do see that we could, you know, this kind of a device could be combined with buprenorphine or some other sort of - the methadone treatment given to women.

Dr. (Jonathan Jarow): Yes. So, to answer your question I can't tell you which type of device is going to get most precedence, but anything that is a medical device. So, if it's software as a medical device, that would certainly be eligible. We'll...

((Crosstalk))

(Atika Permasherin): Okay, great. Thanks.

Dr. (Jonathan Jarow): ...go to the next question.

Coordinator: Our next question comes from (James Elliott). Your line is open.

(James Elliott): Hi. Thank you all for the webinar, and thank you all for working towards this important issue. My question has a little bit to do with the statement you made toward the end of - or toward - at the beginning of the questions about there not being a cash prize associated with this. With the appropriations that came for going towards the opioid epidemic, there are a lot of these types of challenges. HRSA -- within HHS alone -- HRSA Maternal and Child Health has a cash prize challenge for opioid misuse in pregnant moms.

And I'm wondering if participation and acceptance into your Challenge precludes them from going - participants from going into other challenges? Or if participants say in the HRSA challenge, if they get accepted to that would preclude them from participating in the FDA challenge?

Dr. (Michelle Tarver): No, participation in other challenges does not preclude you from participation in this Challenge. The FDA Challenge leads to a marketed device hopefully at the end of the road, which I think all of our federal entities would be supportive and encouraging of. So, no, it would not preclude you from participating in our Challenge.

(James Elliott): Thank you very much.

Coordinator: And as a reminder, I'd like to remind all participants to limit their question to one question due to the high number of questions that we do have. Our next question comes from (Jay). Your line is open.

(Jay): Hi. So, I just want a clarification, then I have a question. When we're talking about opioid use disorder, if you're developing a device -- or novel device --

for treatment of pain, the patient population does not already have to be existing opioid users. Is that correct? That's my understanding.

Dr. (Jonathan Jarow): That is correct.

(Jay): Okay. So, my question is -- thank you for clarifying that -- my question is when I see the application format it appears geared toward startup or some other business model that already is in place. Are you encouraging applications from academic labs, who have not yet created a company structure around this?

Dr. (Jonathan Jarow): Yes.

(Jay): Is there a preference towards one or the other? Because...

Dr. (Jonathan Jarow): No. No, the preference is to the technology that will have the greatest public health impact.

(Jay): Thank you.

(Irene Aihie): We'll take our question.

Coordinator: Our next question comes from (Catherine). Your line is open.

(Catherine): Hi, thank you. I'm wondering if this program can be used to obtain a new or expanded indication for use for an already-marketed product?

Dr. (Michelle Tarver): So yes. We would definitely encourage that if it's a new indication for a product that's already on the market. We would welcome those being submitted as well to this Challenge.

(Catherine): Okay, thank you.

Coordinator: Next question comes from (Andrew). Your line is open.

(Andrew): Hi. Would you be able to elaborate a little bit on what you mean by expedite? Are you talking about also streamlining the amount of design verification testing and maybe even clinical evidence? Or are you just simply talking about the review process itself?

Dr. (Jonathan Jarow): We're talking - in that context we're talking about the review process itself.

(Andrew): Okay.

Dr. (Jonathan Jarow): The statutory requirements for marketing of the device will not change as part of being in this program. However, we make every attempt -- particularly for breakthrough devices -- at pre-market to post-market shift of whatever is reasonable as long as we have reasonable assurance of safety and effectiveness of the product for its intended use at the time of marketing approval.

((Crosstalk))

(Andrew): Okay, thank you.

Dr. (Jonathan Jarow): Next question.

Coordinator: Next question comes from (Edgar). Your line is open.

(Edgar): Hi, this is (Edgar). Thank you for taking my question. My question's around scope. We are working on a device that will help in the treatment and management of opioid-induced constipation. I wonder if that would fall in scope here or that's out of scope?

Dr. (Jonathan Jarow): If you find that - if you can make a justification that this will either help prevent or treat opioid use disorder then yes.

(Edgar): Okay, thank you.

Coordinator: Our next question comes from (Rob). Your line is open.

(Rob): Hi. Thank you for taking my call. Question's around eligibility. You mentioned that medical devices, therapeutic devices, digital health technologies, and a combination (are those) who'd be applicable for this. With that said, you listed four different ones there potentially. Is there more than one winner? Or are you just going to take the best out of those four?

Dr. (Jonathan Jarow): The answer is yes, there will potentially be more than one winner. That's what we're hoping for. The number of applications accepted in the program will be limited by both the quality of the applications that we receive as well as the resources that FDA has at hand to put an all hands on deck approach with each of these applications that are accepted.

((Crosstalk))

(Rob): Thank you.

Dr. (Jonathan Jarow): ...anticipate more than one.

(Rob): Perfect. Thank you.

Coordinator: Our next question comes from (Tracy). Your line is open.

(Tracy): Hi, thanks. I had one question about whether if you apply for this challenge if - are you now committed to follow through with it? Or would you be able to withdraw? And is - will the winners be posted somewhere? And what expectations are there on the winners besides getting the device through quickly? Are there any FDA - other FDA expectations?

Dr. (Jonathan Jarow): So, in terms of the first part of your question, we would prefer that people not withdraw once accepted into the Challenge. But we understand that many devices that are in -- especially at the concept stage -- may never make it to market. So that is, you know, very reasonable. It's not a requirement that you keep developing the product.

On terms of the announcement. Our preference is to be able to announce the names of the companies and the devices that are accepted into the Challenge. But if a company has issues -- or reasons for commercial confidentiality or otherwise -- that they do not want to be announced, we will accept that. Next question.

Coordinator: The question comes from (George). Your line is open.

(George): Thanks a lot for taking my question. I'm coming from a device category already in neuro-modulation. And had a partner who is coming from tool world. And so, our stuff is going to be more brass tacks, device improvement slash innovation in that tool world. You talk about the combo products. I'm already involved in a pivotal trial right now.

But getting the trial design done for a combo product -- I know you say you guys aren't going to be helping much -- but is there some suggestions and advice should you get admitted into this that would be, you know, lead us in the right direction for that?

Dr. (Jonathan Jarow): Absolutely. If you're accepted in the Challenge you would have interactive - interactions with the review division. If you already have a trial started it would be difficult at that point to help you with trial design but yes...

(George): Sure.

Dr. (Jonathan Jarow): ...there would be a lot of input from FDA in terms of your development program. What I meant - I may have misunderstood you -- what I meant by combination products was a drug device combination or a biologic device combination. Or a combination of all three.

(George): No, you're - that's exactly what I was talking about. Talking about a...

Dr. (Jonathan Jarow): Right.

(George): ...naloxone delivery device as...

Dr. (Jonathan Jarow): Okay. Yes. As long as it's - will be regulated by CDRH as a device, yes. It could be accepted into the Challenge. If the primary mode of action is via the drug portion of the combination product, then that wouldn't be accepted into the Challenge. Because that would be regulated by CDER.

(George): Okay. Got it. Thanks so much.

Dr. (Jonathan Jarow): You're welcome. And just for everybody, if you submit an application and we need to find out which center would be regulating it, we do have the ability to get that done in the month-long period we have of the review after September 30. Next question.

Coordinator: Next question comes from (Greg). Your line is open.

(Greg): Hi there. Yes, I think my question has been addressed. Thank you.

Coordinator: Our next question comes from (Michael). Your line is open.

(Michael): Just a quick blocking and tackling question. Are the - is the seven-page limit inclusive of the cover page and executive summary?

Dr. (Jonathan Jarow): Yes.

(Michael): Thank you.

Coordinator: Question comes from (Alan). Your line is open.

(Alan): Hey, thank you for taking my question. Real quickly, we are a Class One device. (Or we'd) be considered a Class One device. We are a currently being prescribed by neurologists working with some form of Marine and Naval fighter pilot veterans.

We've seen positive results. Insurance companies have already started reimbursing for our product. We're going to do a 510k. Should we enter this process? Or should we just move forward with the 510k through the normal I guess route?

Dr. (Jonathan Jarow): Yes. So, to answer your question, you're very welcome to put in an application even for a 510k type device.

The other thing I wanted to make just a general comment, not being part of this Challenge doesn't mean you can't work with the FDA. We encourage people that aren't accepted into the Challenge to interact with the FDA as much as possible. Particularly if it's an early concept.

This can be accomplished through what's called a Pre-Submission Meeting or a QSub meeting to get advice. In addition, there is still the potential for devices to obtain breakthrough device designation outside of the Challenge.

(Alan): Okay. Thank you very much.

Coordinator: Our next question comes from...

((Crosstalk))

Coordinator: ...(Dennis). Your line is open.

(Dennis Heong): Hi Dr. (Jarow). It's (Dennis Heong). For a 510k typically it takes three to four months for clearance. If the device is accepted in the Challenge, what would the review time be?

Dr. (Jonathan Jarow): I can't give you a specific clock. All I could say is that if it's accepted we will do everything in our power to expedite it. But there - this does not change the MDUFA timelines.

(Dennis Heong): Great. Thank you.

Coordinator: Our next question comes from (Alex). Your line is open.

(Alex): Hi. So, I think you've answered part of it. My question's about confidentiality. Is the application held confidential?

Dr. (Jonathan Jarow): Yes. All communications with the FDA would be considered confidential commercial information. And we would not release any of it. In terms of once you're accepted into a - the Challenge, any announcement that we would make would be - we would let the sponsor know about it in advance.

(Alex): Okay. Thank you.

Coordinator: Next question comes from (Jamie). Your line is open.

(Jamie): Yes, hello. We were wondering, we are considering to go the de novo route for our project. And we were wondering if we were to submit the application with this Challenge, can you compare and contrast timelines in terms of review and approval?

Dr. (Jonathan Jarow): Again, the Challenge itself does not change any of the statutory requirements or the MDUFA commitments in terms of timelines. All I can say is that a device that's going to have a significant impact on public health will be expedited as much as possible with an all hands-on deck approach from the FDA. But we can't give you an actual time at this point, because we don't know the quality of your application.

Man: Thank you.

Coordinator: Our next question comes from (Jeff). Your line is open.

(Jeff): Hi, good afternoon. Thanks for taking the question. Just in following some of the (tip) trends that we've seen with the FDA in the past, when differentiation is clearly established sometimes there is (an additional) clearance or designation as to - this is separate from an indication.

But just some form of acknowledgement from the FDA of the intent to use for medical personnel to differentiate between products that are sometimes visually similar. Is there any consideration to that for individuals that work through the process and validate success in opioid reduction?

Dr. (Jonathan Jarow): I'm not quite clear on what you're asking specifically. Anything that would be part of this Challenge would receive labelling claims that would be justified by the evidence that's submitted...

(Jeff): Okay. That's good enough. Same question, so...

Dr. (Jonathan Jarow): Okay.

(Jeff): ...safe. Okay, thank you.

Coordinator: Question comes from (Adam). Your line is open.

(Adam): Yes. A question around, I'm just curious if you've had any discussions with CMS in regards to devices that go through the program? Are they - are there any special reimbursement pathways or new pathways or any color that you might provide on that?

Dr. (Michelle Tarver): So, as you probably are aware we do have the - a parallel review process. So, we would - if the submitter was interested in pursuing that option we

would definitely welcome - help facilitate that conversation at the time. If they are selected into the Challenge.

(Adam): Okay, so if they're innovative devices that fall outside the typical reimbursement pathway, then that's - there's not necessarily been a discussion with CMS about how to accommodate those type of new devices.

Dr. (Michelle Tarver): I think we have to see what we receive as part of the Challenge before we can initiate that conversation.

(Adam): Okay. Thank you.

Coordinator: Question comes from (Michael). Your line is open.

(Michael): Hi, thanks for taking my question. You've actually answered it already for me, so thank you very much.

Dr. (Jonathan Jarow): You're welcome.

Coordinator: Our next question comes from (Justin). Your line is open.

(Justin): Yes, hi. We have an already-commercial device with an indication for pain management. And that's been on the market for a while. We also have a near-completed development of a derivative device, which is going to claim the already-commercial device as a predicate when we apply for clearance for the new device.

If -- in the context of the Challenge -- is there - should we consider one application inclusive of both devices, since they're effectively pursuing the

same indication? Or is two applications for the two separate devices required? Or just maybe some context for how we should think about that.

Dr. (Jonathan Jarow): If you're going to have two separate commercial applications - I'm sorry, if you're going to have two regulatory applications for the two separate devices, then you should put in two separate applications for the Challenge if you think both of them are potentials for that.

(Justin): Okay. Great, thanks.

Coordinator: Our next question comes from (Richard). Your line is open.

(Richard): Hi. My question has been answered. Hello?

Dr. (Jonathan Jarow): Yes, we're here.

((Crosstalk))

Coordinator: And as a reminder, please press star two if you no longer have a question. Our next question comes from (Ken). Your line is open.

(Ken): Thank you for this webinar, it's really, really great. We're wondering about funding. Does the amount of existing funding for a project impact how likely our application is to be selected?

And if so, how much might it contribute to the likelihood of selection for the program? Because that -- to a certain degree -- is under our control. So, we're wondering how much effort that we should focus on that aspect before submission.

Dr. (Michelle Tarver): The amount of money does not impact your - our decision in terms of who would be eligible when selected for the Challenge.

Obviously additional funding may help move the product forward. So, it's something that you still may want to consider as part of your business plan. But it does not impact your eligibility for the challenge.

(Ken): Not eligibility. Likelihood of selection.

Dr. (Michelle Tarver): Neither one. We're looking at the impact of what you submit on public health. And that's what we're focusing on in making our decision. Or one of the criteria.

(Ken): That's wonderful. Yes. Is there a chance that you know of any avenues that this may open up if we're selected? For example, accelerators...

((Crosstalk))

Dr. (Jonathan Jarow): We can't give advice on seeking funding. But our think - we do not - we specifically do not ask whether you're a private company or an academic. You know, the amount of funds available for the development of this product. So, our hope is that potentially being the Challenge would increase your avenues for fundraising.

(Ken): We hope that too. Thank you very much for your time.

Coordinator: Our next question comes from (Chandran). Your line is open.

(Chandran): Hi. Thank you for taking my question. I was just curious kind of following up on some of the other questions on whether there are more specific sort of

criteria on how they applications will be judged? In terms of the list of major topics to cover.

I was curious if certain areas were weighted more than others in terms of development team versus say overall public health impact. Those sorts of questions.

Dr. (Jonathan Jarow): Well the overall - no. There really isn't. The overall public health impact is obviously the priority. But if the device is not feasible and there isn't a realistic development plan in place, that public health impact may be, you know, not carry the day if you will. So...

(Chandran): Right.

Dr. (Jonathan Jarow): ...you know, all the factors are given weight. And what we're looking for is a device that will have the greatest impact and the likelihood of making it to market and benefit from being in the program. Because devices can be developed outside of the program.

(Chandran): Thank you.

Coordinator: Our next question comes from (Shree). Your line is open.

(Shree): Hi there. Thank you for taking my question. I represent a company that makes wearable neuro-modulation devices for post-surgical pain. And I have a question with regards to the device development plan. We are seeking to expand our indications for general post-surgical pain.

However, we also have anecdotal and registry data that we've been able to cut down on opioid use when this device is being used. So my question to you is

-- as part of the development plan -- do we need to say that we have enough clinical data? Or do we have to do a specific opioid reduction clinical trial?

Dr. (Jonathan Jarow): So, I - obviously I can't make a judgement based on just this question alone of what your evidence needs will be. But if you're accepted into the Challenge you could have interactions with the agency that will give some input.

You know, evaluate the data you currently have and give some input as whether additional data or evidence would be - need to be collected. You know, but this is exactly the type of thing we're looking for. You know, an existing device that's already on the market. If you can show a plan to develop it, to demonstrate that it's -- either by opioid replacing or opioid sparing -- could prevent opioid use disorder, this is exactly the type of product we're looking for.

Dr. (Michelle Tarver): And you're welcome to include information that you may have already collected in your feasibility or the public health impact portion as well. And comment on the data sources you may already have available.

(Shree): Okay. May I ask one follow-up question to this please?

Dr. (Jonathan Jarow): I think we're not taking follow-up questions because there's a long list.

(Shree): Okay. Well thank you for your time. Appreciate it.

Coordinator: Our next question comes from...

((Crosstalk))

Coordinator: ...(Suzanne).

Dr. (Jonathan Jarow): Just go ahead.

Dr. (Michelle Tarver): I'm sorry. As a reminder, we do have a mailbox you can send questions to that's listed on the slide.

Coordinator: (Suzanne), your line is open.

(Suzanne): Yes, hello. Thank you for taking my question. I wanted some clarification about the submission. Specifically, the definition of the development team as we describe it. So, the question is, does that - can that also include external collaborators and consultants as part of the development team? Or are you non-specific to that?

Dr. (Jonathan Jarow): No, absolutely. If you already have external either CROs or investigators or whatever lined up, we definitely want to hear about all of that. All the resources that you can bring to bear on the development of this product.

Coordinator: Our next question comes from (Stephanie). Your line is open.

(Stephanie): Hi. Thank you for taking my call. I was just wondering if medical device development tools would be eligible for this program?

Dr. (Michelle Tarver): So, this is geared towards products that would be regulated and marketed in the US market. So, the medical device tool program would be probably a more appropriate place if that's what you think - what you're developing would fit best with.

((Crosstalk))

(Stephanie): Okay...

Dr. (Michelle Tarver):But you can submit...

(Stephanie): ...thank you.

Dr. (Michelle Tarver):...a more specific question to us through the mailbox. We may be able to give you a more fleshed-out response to that.

(Stephanie): Okay, thanks.

Dr. (Jonathan Jarow): But we would definitely encourage you in what you're doing.

Coordinator: Our next question comes from (Eileen). Your line is open.

(Eileen): Thank you. Our prototype is a personalized and tamper-evident storage device for opioids that administers medications in accordance with the prescription. Does this meet the definition of a medical device?

Dr. (Jonathan Jarow): I'm not going to be able to answer that on this webinar. But if you want to submit it to our mailbox we could give you more - which we have a greater - better description, we give you advice whether or not this qualifies as a medical device.

(Eileen): Okay, thank you.

Coordinator: Our next question comes from (Deborah). Your line is open.

(Deborah): Hi. I'd just like some clarification on the application format. In the seven-page limit -- if we actually have designs or schematics of our device -- does that have to be incorporated into the seven pages? Or can those be supplemental?

Dr. (Jonathan Jarow): So, we get asked this question a lot. Any kind of extra stuff that you want to have reviewed you could put links to, whether it be a video or you know, design drawings or whatever. Some people want to include references, you could have a link to that. But the seven-page application should be able to stand on its own, assuming that we do not look at any of the things that you have links to.

(Deborah): Thank you.

Coordinator: Next question comes from (Leslie). Your line is open.

(Leslie): Hi. Quick question on just the maturity of the idea. So, let's say we're coming from an academic center. If we were using an unregulated device as an opiate reduction solution with a potentially, you know, regulated application.

That would not - we would not be disadvantaged in this application as long as the system was regulated needed to go through the approval - FDA approval process.

Dr. (Jonathan Jarow): Correct.

(Leslie): Okay.

Dr. (Jonathan Jarow): You would not be disadvantaged.

(Leslie): Great.

Coordinator: Our next question comes from (Kent). Your line is open.

(Kent): Thank you for taking my question. It's regarding the eligibility, product eligibility. We are currently in the market with a pain management device and have been for a number of years. And we're currently in development of a generation two, which basically will carry the same indications for use but will also give us the opportunity to reduce treatment time, which is advantageous to the practitioner.

So, the question for us is with the committee, will we get - is this an acceptable submission with the committee, given the fact that we're currently in the market with a pain management tool?

Dr. (Jonathan Jarow): Yes. As mentioned earlier, marketed devices are acceptable for this. One of the keys that we may be looking for is a claim that you could be - that the device is either opioid sparing or replacing for patients with either chronic or acute pain.

(Kent): Thank you. We have studies that support that. But just, I mean our indication does not - it talks about pain management. So, no, thank you. You addressed my question.

Dr. (Jonathan Jarow): You're welcome.

Coordinator: Question - the next question comes from (Catherine). Your line is open.

(Catherine): Hi, thank you. Other than the eligibility criteria being different, is this program different from the Breakthrough Devices program? Or is it essentially just another way to get into the Breakthrough Devices program?

Dr. (Jonathan Jarow): So as mentioned on the website, those devices that meet the statutory requirements for Breakthrough designation will automatically receive that without submitting a separate application. But you can into this program without meeting those.

(Catherine): Okay, thank you.

Coordinator: Question comes from (Tracy). Your line is open.

Dr. (Jonathan Jarow): Lost (Tracy). We have (Johnathan) now.

Coordinator: Moment. (Tracy), your line is open.

(Tracy): Yes. My question was about the clinical evidence that's required for the submission. And whether there's any - if there's more weight given to something that reduces opioids or something that reduces addiction?

Dr. (Jonathan Jarow): So, there is no absolute requirement for clinical evidence to be submitted in application and to be part of the Challenge. Obviously, the more evidence that you've collected the easier it is for us to assess the feasibility.

Dr. (Michelle Tarver): And the evidence may come later during the submission - after the application phase but during the regulatory development process. So, when you're developing the product for regulatory submission, that may be where the evidence is collected as well. But it...

((Crosstalk))

(Tracy): Okay, great.

Dr. (Michelle Tarver):...does not preclude entry into the Challenge.

Coordinator: Our next question comes from (Johnathan). Your line is open.

(Johnathan): Hi. I was wondering if you could further characterize what you mean by enhanced interactions with FDA as compares to the existing methods for soliciting early FDA feedback.

Dr. (Jonathan Jarow): So, this would be -- as a previous caller mentioned -- very analogous to the Breakthrough program. And that's why we've put that on the website for that on one of the slides, for resources. So, they would be increased opportunity for both interactions with the review division as well as more attention from senior management.

(Johnathan): Thank you.

Coordinator: Next question comes from (Leslie). Your line is open.

(Leslie): Hi. I just had a question about logistics. So, the Challenge says that the collaboration interaction phase is 90 days. And I was wondering if there's a specific start and end date to that?

Dr. (Jonathan Jarow): So, there's no specific laid out start and end date for that 90 days, but we anticipate that it would occur shortly after announcement. But if the applicant is not ready at that point we would obviously accommodate their needs.

(Leslie): Okay, thank you.

Coordinator: Next question comes from (Jamie). Your line is open. Check your mute button. We'll go to the next question. Mr. (Faust), your line is open.

(Faust): I have a question regarding multiple applications and whether it would be possible to cross-reference between the different applications?

Dr. (Jonathan Jarow): As I stated before, all applications should be able to stand on their own. We do not mind you cross-referencing them, but we can't - depending upon what the concepts are -- the intended use -- it may not be reviewed by the same team.

(Faust): Thank you.

Coordinator: Next question comes from (Alicia). Your line is open.

(Alicia): Hi. Thank you. I have a question about a medical device that is currently marketed and we're seeing a reduction and elimination of opioids with it. And so, my question is just, with the Challenge is there a possibility of increased promotion and awareness of our device through working with the FDA in both the public and medical field?

Dr. (Jonathan Jarow): So, what would happen is if you were seeking expanded claims or a change in labeling. That would be an avenue for this program. If you're just looking to leave a marketed device, everything the same then there would be no regulatory interactions with the agency. And the agency doesn't do promotion itself.

(Alicia): Okay...

Dr. (Michelle Tarver): Right, and the same rules regarding off-label promotion would still apply with this Challenge.

(Alicia): Okay.

((Crosstalk))

Coordinator: Next question comes from (Breethy), your line is open.

(Breethy): Hi. Just had a question about the application process. So, when we submit the application by end of September, do we expect to hear back any - I mean do we have an interactive process review with FDA until they make the announcement in November? Or is it just going to be a final announcement where we just tell who are the (sponsors) selected for this application?

Dr. (Michelle Tarver): So, as we're reviewing, if there are specific questions that the review team has there may be the possibility of them reaching out. But it probably - most of our interaction will be the announcement in November. Because we hope that the seven-page document that you've submitted will answer and address all of our concerns. But there will not be an - it will not be an interactive process after you submit. It'll be a decisional process after that.

Dr. (Jonathan Jarow): But we will be informing all applicants of the final decision regarding their application.

(Breethy): Thank you.

Coordinator: Our next question comes from (Paselo). Your line is open.

(Paselo): Yes, hello. How are you thinking about integrating this Challenge with the team that is leading Software As the Medical Device and future policies for that?

One of the questions would be is if you're a winner of the Challenge and you're developing a Software As A Medical Device, you know, should you actually be going through the SAMD program? Or this Challenge program? Will you be held up while the SAMD team is deciding on future (policies) for all SAMD? How are you thinking about that?

Dr. (Jonathan Jarow): Yes. So, to be very clear, once you're accepted into the Challenge your device will go to whatever regulators within CDRH would be providing input on your development plan.

So, if it's Software as a Medical Device you would interact with the Digital Health team either directly or indirectly through the review division that was assigned your file. So there really is - it's fully integrated. Answer your question directly.

(Paselo): Thank you.

Coordinator: Our final question will come from (Jeff). Your line is open.

(Jeff): Hi. Thanks for taking my question. I have a - my question revolves around something that's actually much later stage in the development process. And if we're looking at, you know, submitting a 510k -- whether it be a special or a traditional for a product -- in the next month or two months here, we don't exactly fit into the window of this Challenge timeline with I think us talking about September 30 deadline for everybody to submit.

What benefits might this program bring to that sort of timeline for a product where we're already having pre-sub conversations and then eventually a submission, but we think we fit into the public health benefit that you've talked about?

Dr. (Jonathan Jarow): Yes. So technically you would be eligible to apply for the Challenge. It's just that the only aspect that you would benefit from being part of this challenge potentially -- depending on what happens with the review - first cycle review of your 510k -- would be to do everything we could to expedite that review. And so...

((Crosstalk))

(Jeff): Yes.

Dr. (Jonathan Jarow): ...you know, there'd be limited benefit from FDA interactions.

(Jeff): Okay. And do you think we should - should that be a topic of discussion for our pre-sub with our actual review department to talk about the public health benefit?

Dr. (Jonathan Jarow): Definitely.

(Jeff): Okay. Thank you very much.

Dr. (Jonathan Jarow): You're welcome.

((Crosstalk))

(Irene Aihie): Thank you...

Coordinator: We have no further questions.

(Irene Aihie): ...this is (Irene Aihie). We appreciate your participation and also questions. Today's presentation and transcript will be made available on the CDRH Learn web page at W-W-W dot F-D-A dot gov, forward slash Training, forward slash C-D-R-H Learn by Thursday, August 2.

If you have additional questions about today's presentation, please use the contact information provided at the end of slide presentation. As always, we appreciate your feedback. Following the conclusion of the webinar please complete a short survey about your FDA CDRH webinar experience.

The survey can be found at W-W-W dot F-D-A dot gov, forward slash C-D-R-H webinar immediately following the conclusion of today's live webinar. Again, thank you for participating. This concludes today's webinar.

Coordinator: Thank you for your participation in today's conference. Please disconnect at this time.

END